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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,648	07/23/2003	Peter B. Heifetz	2075USCON8	9729

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EXAMINER

LUNDGREN, JEFFREY S

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/625,648	Applicant(s) HEIFETZ ET AL.	
	Examiner Jeff Lundgren	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-27 is/are pending in the application.
- 4a) Of the above claim(s) 5-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>see office action</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-4, in the reply filed on April 27, 2006, is acknowledged. Claims 1-4 are the subject of examination; claims 5-27 are withdrawn from consideration as being directed to a non-elected invention.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on August 6, 2004, has been considered by the Examiner. The submission is in compliance with the provisions of 37 CFR § 1.97. Enclosed with this Office Action is a return-copy of the Form PTO-1449 with the Examiner's initials and signature indicating those references that have been considered, however, none of the foreign patent references or non-patent literature documents were presently available, and have therefore been lined through.

Claim Rejections - 35 USC § 112, 1st paragraph (Written Description)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants' claimed invention is directed to all "shuffled" or "mutagenized" DNA sequences encoding herbicide resistant protox enzymes. However, Applicants' disclosure is substantially lacking support for the claimed invention when considered in view of the art. Applicants' examples do little to overcome the understanding in the art, and to show sufficient descriptive support. Example 46 is directed to in vitro shuffled protox genes and only provides guidelines for methods that one of ordinary skill in the art might use to prepare a shuffled protox DNA; no shuffled DNAs are actually prepared by Applicants.

Art Unit: 1639

Although certain genes encoding protox enzymes have recently become known to the art, there is still no clear sequence that reasonably defines protox enzymes as a group (*i.e.*, no reasonable genus sequence). See Lermontova (Lermontova *et al.*, *Proc. Natl. Acad. Sci* 94:8895-8900 (1997)), wherein it is disclosed that sequence similarity between protox I and II only had 27.2% sequence similarity, only share a few identical domains, and elucidates any structure-function relationship that may or may not exist (see page 8898 in section titled, *Discussion*). Further, the structure-function relationship has never been provided by Applicants, and only recently have certain technical features been disclosed to the public. See Randolph-Anderson (Randolph-Anderson *et al.*, *Plant Molecular Biology* 38:839-859 (1998)), where the sequences of various protox genes are compared, pages 849-850).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b)¹ as being anticipated by Dailey *et al.*, *The Journal of Biological Chemistry* 269(2):813-815 (1994).

The claims, such as claims 1 and 3, are directed to DNA molecules that encode a protox (*i.e.*, protoporphyrinogen oxidase) enzyme that has enhanced tolerance to a herbicide that inhibits protox activity relative to another protox enzyme. The claim terms “shuffled” and “mutagenized” are given little patentable weight because these terms are more directed to a process for preparing a DNA rather than the DNA itself, which is the claimed subject matter. Claims 2 and 4 require that the increased tolerance to a diphenylether.

Dailey teaches an engineered DNA molecule that encodes an herbicide resistant protox gene, wherein the gene has protox activity (see section titled *Materials and Methods*). Dailey teaches that the gene has increased resistance to protox herbicides, as in claims 2 and 4.

¹ Applicants' claimed invention encompasses embodiments filed greater than one year after Dailey *et al.*, but not disclosed in the 08/261,198 CIP priority application.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Oshio *et al.*, *Zeitschrift fuer Naturforschung, C: Journal of Biosciences* 48(3-4), 339-44 (1993).

The claims, such as claims 1 and 3, are directed to DNA molecules that encode a protox (*i.e.*, protoporphyrinogen oxidase) enzyme that has enhanced tolerance to a herbicide that inhibits protox activity relative to another protox enzyme. The claim terms “shuffled” and “mutagenized” are given little patentable weight because these terms are more directed to a process for preparing a DNA rather than the DNA itself, which is the claimed subject matter. Claims 2 and 4 require that the increased tolerance to a diphenylether.

Oshio teaches a wild-type and mutant strain of *Chlamydomonas reinhardtii* RS-3. Both strains have a nucleic acid that encodes for a protox enzyme, wherein the protox enzyme of the mutant strain has increased resistance to diphenylether herbicides (see pages 339-340, and 343).

Conclusions

No claim is allowable.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (*e.g.*, if the amendment is not supported *in ipsius verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.


Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1639

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JSL



My-Chau Tran
Patent Examiner